Remarks

I. Status of the Claims

Claims 1-8, 17-23 and 32-37 are pending in the application. Claims 1-8, 17-23, 32, 34, 36 and 37 stand rejected.

II. Claim Rejections Under 35 U.S.C. § 103

Claims 1-8, 17-23, 32, 34, 36 and 37 are rejected under 35 U.S.C. § 103 as being unpatentable over Kim et al. (WO 99/20745) in view of Chen et al. (U.S. Patent No. 5,922,352) and Sangekar et al. (U.S. Patent No. 4,992,277). Applicants respectfully traverse the rejection.

The cited references do not disclose or suggest the claimed invention. The claimed invention is a delayed burst release dosage form comprising a compressed core in the form of a tablet or capsule and an overcoated shell portion,

wherein said overcoated shell portion comprises a composition comprising 40 to 95 weight percent of a high molecular weight water soluble polymer having a weight average molecular weight from about 140,000 to about 1,150,000 and a cloud point from about 20 to about 90° C,

5 to 25 weight percent carrageenan, and

0.5 to 5 weight percent gellan gum,

wherein said core comprises a pharmaceutical active ingredient selected from analgesics, anti-inflammatory agents, antiarthritics, anesthetics, antihistamines, antitussives, antibiotics, anti-infective agents, antivirals, anticoagulants, antidepressants, antidiabetic agents, antiemetics, antiflatulents, antifungals, antispasmodics, appetite suppressants, bronchodilators, cardiovascular agents, central nervous system agents, central nervous system stimulants, decongestants, oral contraceptives, diuretics, expectorants, gastrointestinal agents, migraine preparations, motion sickness products, mucolytics, muscle relaxants, osteoporosis preparations, polydimethylsiloxanes, respiratory agents, sleep-aids, urinary tract agents and mixtures thereof,

wherein said overcoated shell portion provides for a delayed release of the active ingredient from the dosage form such that release of the pharmaceutical active ingredient is

delayed for a predetermined time after ingestion and wherein after said predetermined time said pharmaceutical active ingredient is promptly released.

Kim et al. discloses enteric coated granules prepared by coating lactic acid bacteria-containing seed with a water-miscible coating material. See Abstract. Kim et al. discloses that the water-miscible coating material may be hydroxypropylmethylcellulose or gellan gum (see pages 4-5) and that the amount of coating is preferably 1-80% by weight with respect to the seed (see page 5). Kim et al. discloses that the granule can be coated with a second coating containing a controlled release material (id.), that the controlled release material may be hydroxypropylmethylcellulose, carageenan or guar gum (see page 6), and that the amount of second coating material is 1 to 95% by weight with respect to the first coated granule (see page 7).

Kim et al. does not disclose a dosage form comprising an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a high molecular weight water soluble polymer having a weight average molecular weight from about 140,000 to about 1,150,000 and a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum as claimed.

Chen et al. discloses a controlled release dosage form that contains a core having delayed release properties which contains a calcium channel blocker compound mixed with an enteric polymer in aqueous medium dispersed onto a solid pharmaceutical diluents to form a granulation that compressed into a tablet and used as the delayed releasing core of the invention. See col. 1, lines 60-67; and col. 3, lines 4-8.

Like Kim et al., Chen et al. does not disclose a dosage form comprising an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a high molecular weight water soluble polymer having a weight average molecular weight from about 140,000 to about 1,150,000 and a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum as claimed.

Sangekar et al. discloses an immediate release diltiazem tablet that includes a swellable hydrophilic polymer. See Abstract and col. 2, lines 62-68. Sangekar et al. discloses that "[e]xamples of swellable hydrophilic polymers include: hydroxypropylmethyl cellulose; hydroxypropyl cellulose; methyl cellulose; hydroxymethyl cellulose; and hydroxyethyl cellulose, *which can be used alone or in combination*; carboxymethyl cellulose

and the sodium salt thereof, *which can be used alone or in combination*; and other hydrocolloids, such as acacia and guar gum." See col. 3, lines 1-10 (emphasis added).

Like Kim et al. and Chen et al., Sangekar et al. does not disclose a dosage form comprising an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a high molecular weight water soluble polymer having a weight average molecular weight from about 140,000 to about 1,150,000 and a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum as claimed.

The present specification discloses that a variety of cellulosic polymers are known to be useful in the preparation of dosage forms and that such polymers are often combined with other polymers and used as coatings or shells for dosage forms. See page 1, lines 23-25. The specification goes on to disclose that such compositions are often difficult to use because their viscosity becomes too high. See page 2, lines 23-28. The specification further discloses that the composition of the invention as claimed is manageable and has desirable properties. See page 2, line 29 to page 3, line 11. Reconsideration and withdrawal of the rejection of claims 1-8, 17-23, 32, 34, 36 and 37 under 35 U.S.C. § 103 over Kim et al. (WO 99/20745) in view of Chen et al. (U.S. Patent No. 5,922,352) and Sangekar et al. (U.S. Patent No. 4,992,277) are respectfully requested.

III. Claim Objections

Claims 33 and 35 are objected to under 37 C.F.R. § 1.75 as being of improper dependent form for failing to further limit the subject matter of a previous claim. In response, Applicants submit that the cancellation of claims 33 and 35 obviate any basis for the objection thereto. Reconsideration and withdrawal of the objection to claims 33 and 35 under 37 C.F.R. § 1.75 are respectfully requested.

IV. Conclusion

Early consideration and prompt allowance of the claims are respectfully requested.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5007USCIP1/LAD.

Respectfully submitted,

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